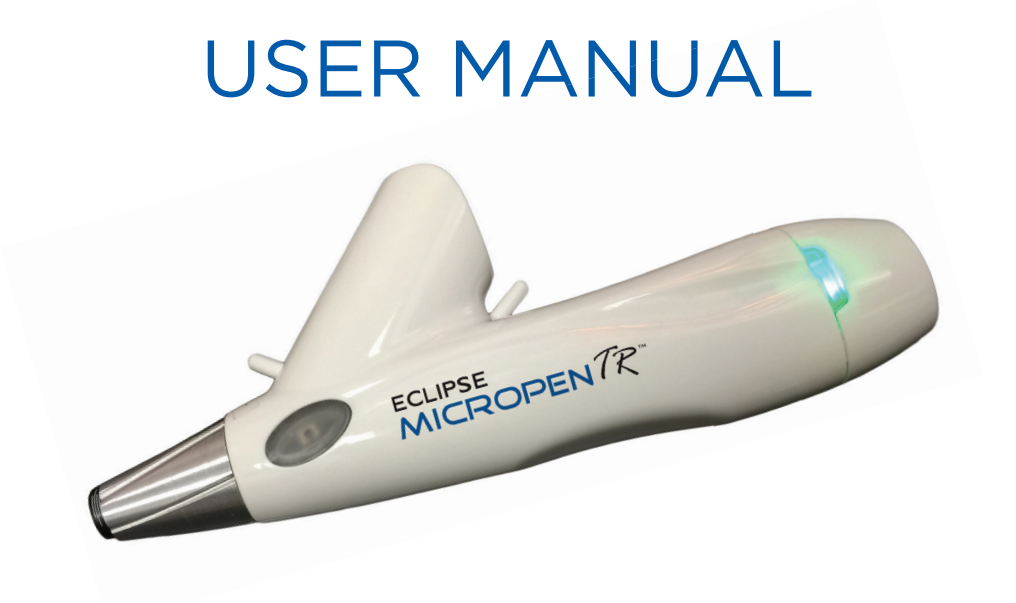
ECLIPSE MICROPEN TR™ TATTOO REMOVAL

USER MANUAL



Don't regret it... Remove it!

METR
Mechanized Epidermal Tattoo Removal

ECLIPSE
AESTHETICS

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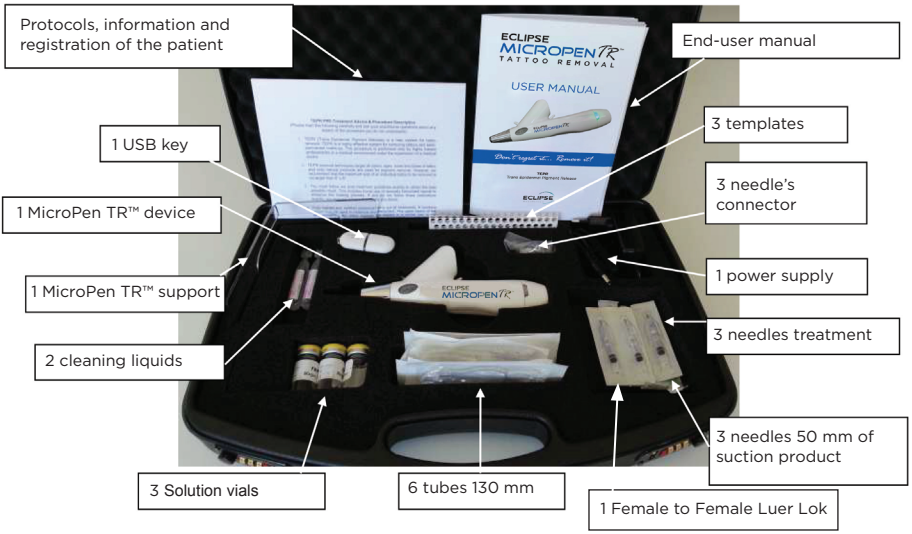
1. Unpacking Your Eclipse MicroPen TR™

Thank you for choosing the Eclipse MicroPen TR™. Please check the case contents as follows. Make sure that your case includes:



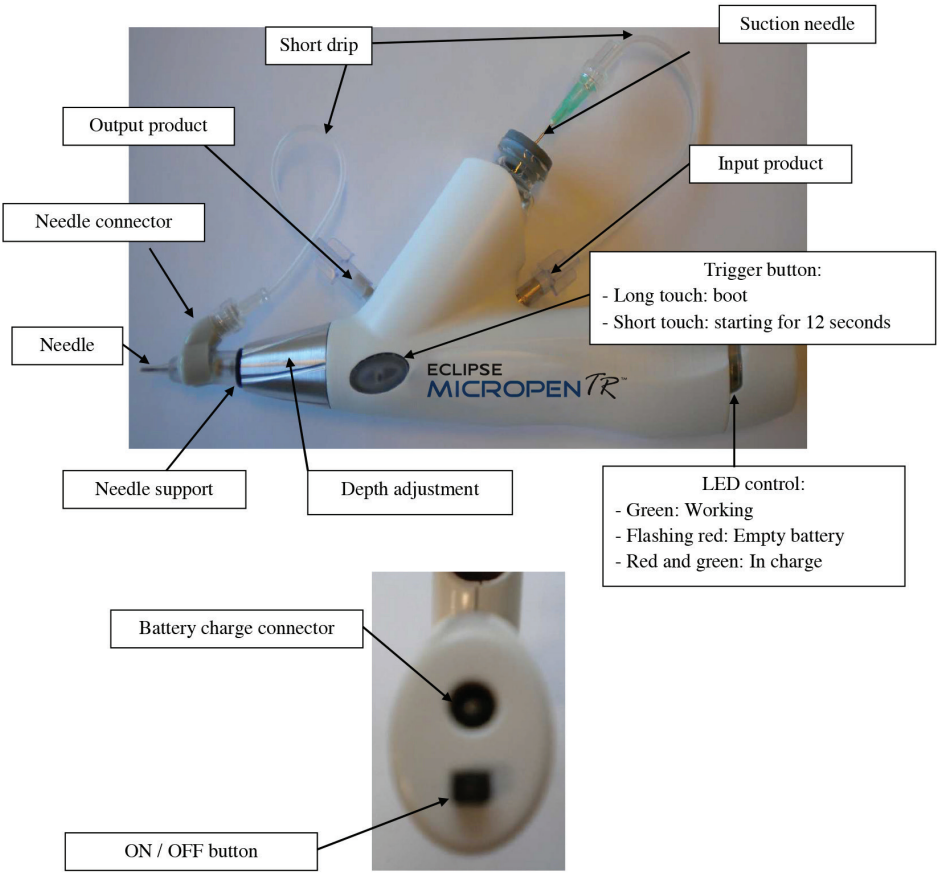
INTRODUCTION

The *Mechanized Epidermal Tattoo Removal* (*METR*) technique is a modern version of an old technique used to remove tattoos. The technique is based on the theory of localized partial healing. Its advance over original methods is to rely upon small surface area, closely spaced partial thickness injuries with intervening skin bridges to return the tattooed area to normal skin color. The use of closely spaced needles, similar to those used in traditional tattoo devices, is necessary to obtain defined penetration depths. The needles facilitate penetration of the tattoo target to a defined depth where the special Tattoo Removal MicroPen TR™ fluid is introduced.

The tattooed area will reject the ink through cutaneous exfoliation and produce a scab or eschar. The treated area will heal over a period of 2 to 3 weeks and the scab will fall away leaving clear skin beneath.

Repeat treatments are scheduled to treat the remaining pigmented areas. This technique allows the whole area of the tattoo to be progressively and sequentially covered, and then removed, in three-five sessions. A secondary healing phase commences using a silicone topical to control desired healing characteristics.

2. DESCRIPTION

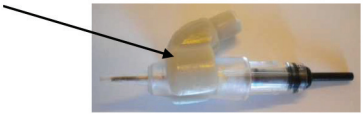


3. SETTINGS

Assemble the MicroPen TR™ as follows:

1) Attach the needle connector to the needle

The needle supplied with the MicroPen TR™ as a fixation system in its upper part.



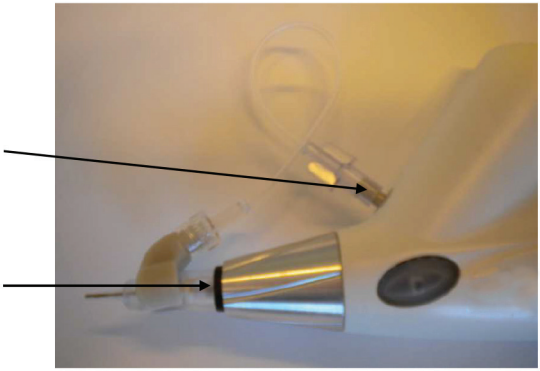
2) Connection of the tube to the needle connector

Screw the short drip in the needle connector.

3) Connection of the needle to the MicroPen TR™

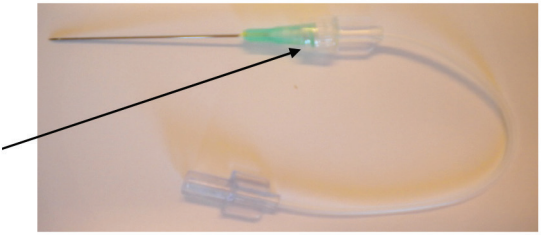
Connect the tube to the output product.

Insert the needle inside the needle support. The needle must be pushed up and fully seated into the nose assembly.



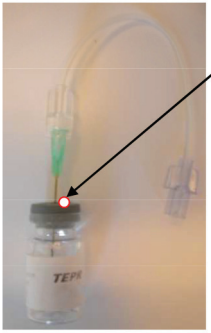
4) Connection of the suction needle to a tube

Screw the tube to the suction needle.



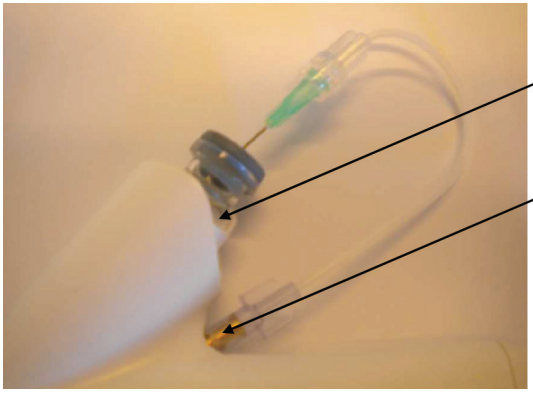
5) Connection of the suction needle to the vial

Remove the cap and pierce the vial membrane with the suction needle.



NOTE: *Allowing some air into the vial may be necessary to obtain a regular flow of product to the needle.*

6) Set up the *METR* vial

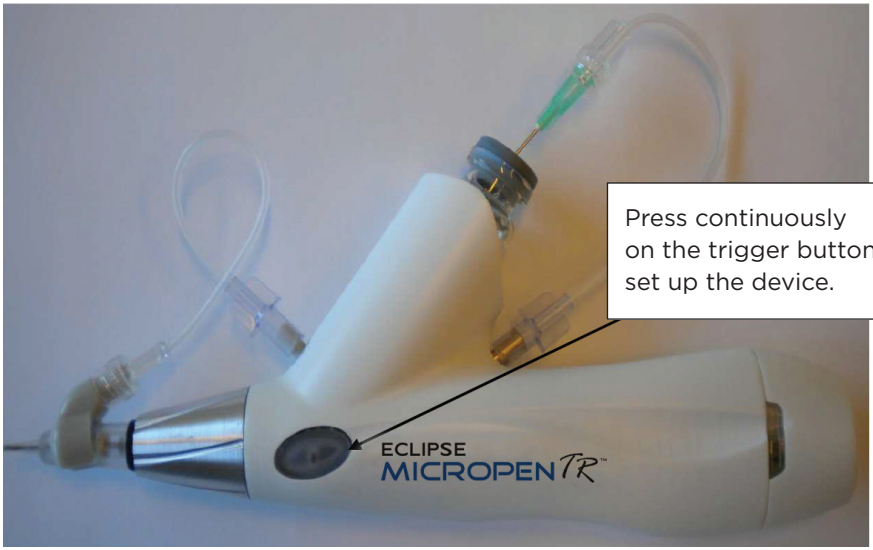


Insert the vial in the upper housing chamber of MicroPen TR™.

Connect the tube to the input port.

3 .1 SET UP

To prepare the MicroPen TR™ for use, POWER on the device. A green light shows current ON. PRESS continuously on the trigger button until the solution appears at the needle. Check for the presence of air or fluid in the supply tube. This process may take up to 30 seconds.



NOTE: *It is necessary to set up the device before each session by PRESSING continuously on the trigger button to prime the fluid reservoir.*

THE OPERATOR SHOULD VISUALLY CONTROL THE AMOUNT OF FLUID IN THE NEEDLE RESERVOIR

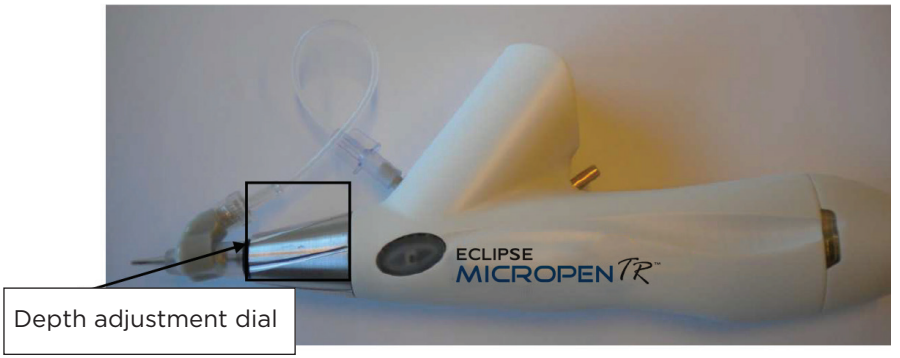
4 – USING THE MICROPEN TR™

4.1 ADJUSTING THE SPEED OF THE MOTOR

The speed must be adjusted when the motor in the ON position. Once the device is switched ON, maintain continuous pressure on the ON/OFF button. The motor will cycle from the minimum to the maximum speed. Release the button when the correct speed is attained.

4.2 ADJUSTING THE INJECTION DEPTH

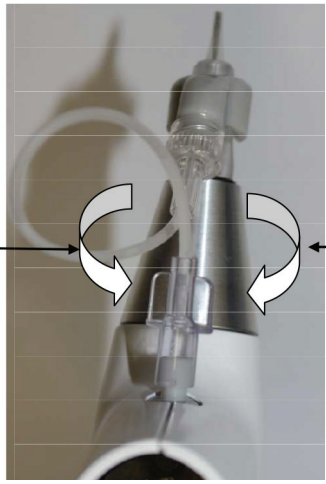
In order to treat different kind of tattoos and skin types, the injection depth of the MicroPen TR™ is adjustable. Each turn of the depth adjustment represents an increase or decrease. To adjust the depth, use the “depth-adjustment dial.”



Progressively INCREASE depth by rotating from left to the right. Progressively decrease by rotating from right to the left.

Rotation from the left to the right:

+ DEEP



Rotation from the right to the left:

− DEEP

VISUAL CONTROL OF THE DEPTH SETTING IS IMPORTANT BEFORE ANY TREATMENT

5 – IMPORTANT INFORMATION FOR PATIENTS

Removing tattoos induces a definitive visual modification of the body. It is important to explain to the patient all aspects of the treatment phase and the aftercare regimen required to ensure a successful result.

An informed consent document should be reviewed by the patient and signed. See ***Advice and Procedure Description*** documents.

ONLY ADULT PATIENTS WHO ARE OVER 18 YEARS OF AGE ARE ELIGIBLE FOR TREATMENT. PARENT OR GUARDIAN CONSENT IS REQUIRED FOR UNDER-AGE PATIENTS.

5.1 - Preparation of the Patient before treatment
Treatment with MicroPen TR™ should be preceded by a review of the patient care instructions and compliance rules for a successful outcome. Use the document package supplied with pen to ensure the patient is adequately informed about risks and benefits.

6 – CHARGING THE BATTERY

The MicroPen TR™ is equipped with an internal Lithium/Ion battery which has a life of 2 hours treatment time.

The battery level is indicated by the light indicator on the device:
- Full battery: Green Light
- Empty battery: Red flashing Light
- On charge: Green and red Light simultaneous

When a red flashing light appears, the battery should be recharged by plug the power supply into the mains. Charging time is approximately about 1 hour.

NOTE: MicroPen TR™ may be used while the battery is charging.

7 – MAINTENANCE

If MicroPen TR™ is not used daily, the system should be 'bled' to remove old treatment fluid. Place the suction needle in sterile solution (saline or sterile water) and press the trigger button for 40 seconds in order to flush any old fluid from the needle.

Regularly clean the device with a soft, lint-free wipe or cloth. Do not use proprietary cleaning solution on any component of MicroPen TR™.

Parts in contact with patient must be changed between each patient or sterilized according to the manufacturer's instructions.

SINGLE-USE PARTS: MICROPEN TR™ NEEDLE – SHORT DRIP – SUCTION NEEDLE

– METR VIAL MUST BE CHANGED BETWEEN EACH PATIENT.

REUSABLE PARTS: NEEDLE CONNECTOR MUST BE REPLACED OR DECONTAMINATED IN A COLD SOLUTION OF 2% GLUTARALDEHYDE BEFORE EACH USE.

Please check individual state, local, federal and country regulations for correct care and sanitation of each component used in the MicroPen TR™ process.

MicroPen TR™ and the battery are guaranteed for one (1) year from the date of purchase.

The MicroPen TR™ components and its battery are subject to strict environmental rules and should be disposed of according to local, state, federal and country regulations.

8 – CAUTIONS & WARNINGS

THE OPERATION OF MICROPEN TR™ IS STRICTLY LIMITED TO HEALTH CARE PROFESSIONALS WHO HAVE RECEIVED SPECIFIC TRAINING IN THE USE OF THE DEVICE AND HAVE BEEN CERTIFIED BY THE COMPANY OR ITS REPRESENTATIVE.

All users must know and understand the risks and contraindications associated with MicroPen TR applications and treatments. The *METR* fluid product used with the MicroPen TR must not come in contact with the eyes, the mouth or mucous membranes. In case of accidental contact, rinse well with water.

ONLY THE *METR* FLUID PRODUCT SUPPLIED BY THE MANUFACTURER OF THE MICROPEN TR CAN BE USED BY THE HEALTH CARE PROFESSIONAL SUPERVISING THE TREATMENT.

Failure to adhere to this warning, absolves the manufacturer of any and all liability.

The practitioner must acknowledge the possibility of a negative or a partial result.

Risks of bad healing, hyperpigmentation, hypopigmentation or allergies to the technique can occur. Please review the supplied documentation covering Risks and Contraindications to treatment.

9 – CONTRAINDICATIONS

The *METR* treatment is contraindicated for the following conditions: - Pregnancy
- Patients who has demonstrated allergy to hydroxypropanoic acid
- Patients who has demonstrated healing difficulties
- Patients with suppressed immune response
- Patients with hemophilia

It is necessary to be particularly vigilant for the following patients:
- Diabetic patients
- Patients with poor healing capacity
- Patients undergoing long-term steroid treatment
- Patients immunocompromised either through drug or disease

10 – GENERAL FEATURES

10.1 IDENTIFICATION

Model: TR1000

- Manufactured for:
  Eclipse Aesthetics, LLC.
  13988 Diplomat Drive, Suite 160
  Dallas, Texas 75234
  800-759-6876

Owner of the homologation:
BFP Electronique
Pole Technnologique de Vimenet
48100 MONTRODAT - France
+33 (0)4 66 32 44 99

- Manufacturer of the device: Idem

10.2 GENERAL CONFIGURATION

- Model reference: MicroPen TR™ Tattoo Removal

- Serial number: MG amm-0000

11 – TECHNICAL CHARACTERISTICS

Dimensions : 23 x 10 x 3 cm
Weight: 170 g
Voltage: 5 V =
Protection: IP 20
Power: 8 W
Battery:
Type: Li-Ion
Capacity: 0.80 Ah
Autonomy: 2 hours
Charging time: 1 hour
Charge voltage: 5 V
Electric security: (type B)

WARNING: Refer to instruction manual

Identification of waste electrical and electronic equipment

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